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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,886

04/05/2004

Christian E. Gruber

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3859

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7590

06/13/2006

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WASHINGTON, DC 20005

EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/816,886	Applicant(s) GRUBER ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54-123 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 54-123 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/21/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The preliminary amendment filed 3/11/2005 has been entered. Claims 54-123 are pending.

#### ***Information Disclosure Statement***

1. The reference AO2 lined through on PT0-1449 filed 4/21/2005 was not considered, because the English translation was not provided.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 54-111, 113, 114, 116, 118-119 and 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al. (5,968,784, issued October 19, 1999).

Spinella et al. disclose a method of identifying gene expression patterns in mRNA populations (See the Abstract). The method involves preparing double-stranded cDNA from an

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mRNA using a primer, cleaving the double stranded cDNA with a first restriction enzyme at a site within the cDNA sequence and not within the primer and inserting the cDNA into cloning vector (See column 5, lines 37-55). The primer used to prime cDNA has a cleavage site for a priming restriction endonuclease (See column 6, lines 4-7). The primer of Spinella et al. is immobilized to a biotin/avidin magnetic bead (See fig. 2). This teaching is inherent that the primer has ligands and cleavage sites. The priming restriction endonuclease is *NotI* (See column 6, lines 22-21). The reverse transcriptase is MMLV-H-RT (See column 16, lines 62-64). The solid support is magnetic beads (See fig. 2). The sticky end is a *NotI* sticky end and the vector has a *NotI* compatible end and a blunt end (See fig. 2). The vector can be plasmids (See column 11, lines 13-16).

Spinella et al. also discussed that a cDNA copy of mRNA is made using a polydT primer, which is then biotinylated. The biotinylated cDNA is then bound to streptavidin beads to remove the rest of the sequence (See column 4, lines 7-14) in the method of SAGE.

Spinella et al do not explicitly disclose the primer-adapter nucleic acid molecule. Since the primer-adapter nucleic acid molecule is not defined in the specification, the teachings of the primer of Spinella et al. meet the limitations of the primer-adapter as claimed.

Spinella et al also do not disclose contacting one or more of the cDNA molecules with at least one hapten to produce one or more hapten-cDNA molecule complex. However, as claimed in claims 110, 113, 118, and 121 hapten is avidin or streptavidin. The discussion of Spinella et al. above meet the limitations of the claims.

Further Spinella et al do to disclose the method step order as claimed, for example, in claim 54, the cDNA molecule is contacted to hapten bound to solid support and then the cDNA

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is cleaved. However, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (In re Burhans, 69 USPQ 330; CCPA 1946) - see, e.g., MPEP 2144.04 (d).

Spinella et al. do not explicitly disclose the cleaved cDNA molecule comprising one sticky end and one blunt end.

Spinella et al. disclose that T4 DNA polymerase is used to generate blunt ends.

One of ordinary skill in the art would have been motivated to apply the method of Spinella et al. to make one or more cDNA molecule because the method of Spinalla et al. allows mRNAs detection with low copy number, permits the generation of global gene expression profiles in a reasonable length and time (See column 5, lines 5-20). It would have been prima facie obvious to make one or more cDNA as claimed.

4. Claims 112, 115, 117, 120 and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al. (5,968,784, issued 10/19/1999) as applied to claims 54-111, 113, 114, 116, 118-119 and 121-122 above, and further in view of Ando et al. (Journal of Clinical Microbiology, March 1997, Vol. 35(3), pg. 570-577).

The teachings of Spinella et al. are set forth in section 3. Spinella et al. do not disclose using SuperScript reverse transcriptase in the method.

Ando et al. disclose a one tube- RT-PCR method that permits routine amplification of the 3-kb region of genetically distinct SRSV strands present in low concentrations in stool samples (See pg. 570, column 2, second paragraph). The key element of the method is that first strand

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cDNA is synthesized with SuperScript II version of Rnase H<sup>-</sup> Moloney murine leukemia virus reverse transcriptase (See the Abstract).

One of ordinary skill in the art would have been motivated to modify the method of Spinella et al. by applying reverse transcriptase, SuperScript because Ando et al. disclose the method which uses reverse transcriptase, SuperScript, permits routine amplification of the 3-kb region of genetically distinct SRSV strands present in low concentrations in stool samples (See pg. 570, column 2, second paragraph). It would have been prima facie obvious to use reverse transcriptase, SuperScript for making cDNA molecule.

### Summary

5. No claims are allowable.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Joyce Tung  
June 7, 2006

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

6/8/06